

Food and Drug Administration Washington, DC

FEB 2 2 2002

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Andrew Kimbrell, Executive Director The Center for Food Safety 660 Pennsylvania Avenue, S.E. Suite 302 Washington, DC 20003

Dear Mr. Kimbrell:

This is in response to your letter of December 17, 2001, regarding the labeling of irradiated food. You expressed concern about the Food and Drug Administration (FDA) changing the current regulations governing the labeling of irradiated foods.

As you may be aware, irradiation labeling was identified as one of the Center for Food Safety and Applied Nutrition's 2001 program priorities and is listed again in our 2002 priorities. FDA has conducted a review of the comments received in response to the Advanced Notice of Proposed Rulemaking on irradiation labeling and has reviewed the results of the focus group research. FDA has not reached any final decision on whether the regulations governing the labeling of irradiated foods should be changed.

Thank you for your letter expressing your concerns about labeling regulations governing irradiated food products. We will forward a copy of your letter to our Dockets Management Branch and will consider all comments before we make a final decision.

Sincerely yours,

Christine Taylor, Ph.D.

Director

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety and Applied Nutrition

98N-1038

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December 17, 2001

Dr. Bernard Schwetz, Principal Deputy Commissioner U.S. Food and Drug Administration 14-71 Parklawn Building, 5600 Fishers Lane Rockville, MD 20857

Mr. Joseph Levitt, Director Center for Food Safety and Applied Nutrition U.S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

Dr. Kenneth Falci
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Re: food irradiation labeling

Greetings,

Dr. Alan Rulis Office of Food Additive Safety, CFSAN U.S. Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740-3835

Dr. Laura Tarantino
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On behalf of the many tens of thousands of consumer members of our two organizations, we submit these comments in opposition to suggestions that FDA should changing the labeling regulation covering all irradiated foods. Suggestions from Congress have urged changing the wording of the label from "irradiated" to "cold pasteurized" or "electronically pasteurized." These suggestions contained in a conference report are, of course, not binding law and if followed would amount to interference in a matter clearly within your discretion. We previously urged you to refrain from making the suggested change by comment letter of June 1 of this year and provided detailed evidence as to why such a change would be misleading. By this comment letter we would like to bring new evidence to your attention.

Peter Jenkins and Mark Worth of our offices earlier served on the advisory group for the FDA food irradiation labeling focus groups. The agency impaneled six separate groups of consumers this past summer in suburban Washington, DC; Sacramento, California; and Minneapolis,

Minnesota. According to earlier published reports, consumers in all three locations unanimously rejected the proposed use of euphemisms, calling them "sneaky," "misleading," and "deceptive."

We highlight here the key portions of the certified transcripts we have received for five of these sessions (the sixth has not been delivered to us, despite several requests). Note that each of the verbatim excerpts is from the portion of the discussion when the participants addressed the Moderator's handout from FDA (described as Handout C) suggesting the use of "cold" or "electronic" or "ion pasteurization" in place of "irradiation" on the label.

### Maryland, June 18 - 6:00 p.m.

MODERATOR: Okay. So now I want to show you the last one. This is the end of our discussion, C.

A PARTICIPANT: Sounds like we're going to end up on 20/20 or something.

(Laughter.)

(General discussion while passing out handouts.)

A PARTICIPANT: This one's not permissible. This one's deceitful.

MODERATOR: Why do you say so?

A PARTICIPANT: Pasteurization is not going to translate in anybody's mind to irradiation.

A PARTICIPANT: No. A PARTICIPANT: No.

A PARTICIPANT: What are they going to do with it?

A PARTICIPANT: You can see the thoughts going through the manufacturer's head, who will want to satisfy the FDA's labeling without using a word that has that "R".

A PARTICIPANT: They use electronic or ion (indiscernible).

MODERATOR: So what do you have here? Electronic pasteurization, cold pasteurization, ion pasteurization. So what do you think. Is it a good idea for the label?

A PARTICIPANT: No.

A PARTICIPANT: What did you say that it means, electronic pasteurization?

A PARTICIPANT: I'm speculating that all these pasteurization words are code words for irradiation.

A PARTICIPANT: That's deceitful.

A PARTICIPANT: Verv.

(Simultaneous discussion.)

A PARTICIPANT: Everything that we see here, we know it's radiation, so we don't want to call it something else.

(General consensus in simultaneous discussion.)

A PARTICIPANT: Why don't they call it what it is?

A PARTICIPANT: That would be just another way --

A PARTICIPANT: Lose your credibility.

A PARTICIPANT: Be careful about the words you pick to say radiation, but you should not pick a word that conceals that it's irradiated.

A PARTICIPANT: And something with that name, I can see a whole mass of people putting on a suit, getting the FDA -

(Simultaneous discussion.)

A PARTICIPANT: Pasteurization is what most people think is a good word. If your milk is pasteurized, then you're thinking that's good, and it comes from Louis Pasteur, and that word is a

MODERATOR: Do you have any idea what is this pasteurization? What kind of process is this?

(Simultaneous discussion.)

A PARTICIPANT: Here's handout number one. Traditional thermal techniques, such as pasteurization.

MODERATOR: Okay, so this is why it's deceiving, because pasteurization is something traditional --

A PARTICIPANT: And it's thermal.

MODERATOR: -- but here it says "cold pasteurization".

MODERATOR: I have one more question. If you'll go to your handout C. We have on the label "treated by cold pasteurization" and then in parentheses, we have "irradiation". Would this help consumers understand what is the process?

A PARTICIPANT: It would let us know it was treated by cold pasteurization and radiation. But what if they don't know (indiscernible)?

A PARTICIPANT: I think it's nasty trying to mask this.

A PARTICIPANT: Yeah, they're making it --

(Simultaneous discussion.)

A PARTICIPANT: Bad choice.

A PARTICIPANT: People don't understand.

A PARTICIPANT: The basis of the thing, you are using radiation to do these different types of things to your meat, your milk, your fruits and your vegetables and all that kind of stuff. Why cover it up? The consumer needs to know what they're getting. And you're just going to put it in parentheses? I don't think so.

A PARTICIPANT: What it will do is make people think, oh well, irradiation must just be pasteurization. They've been doing that to milk all the time. It must be safe. That's just going to make you assume it is safe. That's taking that negative tone that we talked about, radiation, off of the word, because you put it behind pasteurization (indiscernible).

A PARTICIPANT: I just don't think consumers need to be deceived. It needs to be straight out, point blank what it is, and let the consumer make their decision, it's something that I want to try. A PARTICIPANT: Absolutely right. The choice between "treated by cold pasteurization" and "treated by cold pasteurization (radiation)" is a difference between a lie and a bad lie. An unsuccessful lie.

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### Maryland, June 18 - 8:00 p.m.

MODERATOR: And now I would like to show you proposition C. So we can put the other ones away. Pass this around, here you are. Option C is similar to options A and B, except that different terminology is substituted for the words radiation or irradiation. And you can see the examples. So for example, it's "Treated by electronic pasteurization," "Treated by cold pasteurization," "Treated by ion pasteurization." So what do you think about this? What do you think about this idea?

A PARTICIPANT: Sneaky. MODERATOR: Sneaky?

A PARTICIPANT: Yeah, it is. I agree with that.

MODERATOR: Why do you say so? A PARTICIPANT: Why did I say so?

MODERATOR: Um-hmm.

A PARTICIPANT: Well, first, a treatment like cold pasteurization, that's the opposite of what pasteurization is. They heat it. The process of pasteurization, you heat something to a certain temperature, it kills the germs. You can't have cold pasteurization. So you'd have to throw that one out. Electronic pasteurization, that's more believable.

A PARTICIPANT: Sounds like they hooked a probe up.

A PARTICIPANT: Yeah, it does. Shoot it, zap it with something.

MODERATOR: What are your views?

A PARTICIPANT: I think it's totally unbelievable. It's, it has the potential to make people worry about pasteurization, rather than making them feel good about irradiation, if, especially when people started, if a concerted campaign came out from some groups about irradiated food, which there's a good chance it would, once people started connecting irradiation with pasteurization, pasteurization could become suspect, and that could lead to very poor quality milk and certain other foods. So I'd be very much against it.

MODERATOR: And Kelly, what do you think about it?

A PARTICIPANT: I agree with everything you just said. This is **not clear**. I wouldn't know, being a consumer walking in the store, to be honest with you, I don't think I'd catch on that they're one and the same. I wouldn't have known that. And then once things started coming out in the news, I would be -- I would do exactly what you just said. This would be curious -- wait a minute. I'd be asking a lot of questions about my milk, or, is this really doing the process that irradiation was supposed to be doing? Is it going to really make it safe? Less germs and stuff? MODERATOR: And Joann, what do you think?

A PARTICIPANT: I agree with Kelly and John, because -- is this supposed to be the same as irradiation?

MODERATOR: Yeah, the same thing.

A PARTICIPANT: No, see, I wouldn't even -- what is this stuff that's in here. Now, I know what radiation is, and I know a little bit about pasteurization, but if they're trying, like Allison said, it's kind of sneaky.

MODERATOR: Different terminology.

A PARTICIPANT: I don't see it as different terminology. You're usurping one terminology for another purpose. So it's a completely different process. Allison said it. It's sneaky.

A PARTICIPANT: Yeah, when I read it, my first thought was, pasteurization! Like, I didn't know what to think. Also, I'd feel really nervous, because I'd start reading everything and I'd be distrustful of — when it comes to substitute a word that people don't know because they know what they don't want.

MODERATOR: And Karen, what do you think? If you see those statements on the label, would it make you buy this food?

A PARTICIPANT: No. It's misleading.

MODERATOR: But would you know what it is if it was treated by electronic pasteurization (indiscernible), what would you think? What would people think? We have this on the label: "Treated by electronic pasteurization." A consumer comes to the store and sees this on the label. What kind of things it would make you?

A PARTICIPANT: Well I would think that people would be misled, that if you're thinking, but you don't really know, you say well, this product has been pasteurized or something, they might think it's the same as milk, or the same process basically, maybe a little different. I don't think that it really explains what the irradiation is. Or they're not sure, irradiation, there's a difference between that product and something else. People are familiar with that. This, they might link it to the carton of milk being (indiscernible) or whatever. So it is misleading.

### California, July 9 – 6:00 p.m.

MODERATOR: Okay. Now please, let's see at -- let's look at C. Of course, it will be with the same sign. I don't have to repeat. But it will have different statements. Yeah. And let's see what we have here. Treated by electronic pasteurization. Treated by cold pasteurization. Treated by ion pasteurization. What's your reaction? What do you think about this type of labeling irradiating your food?

A PARTICIPANT: They're trying to use an alternative people are comfortable with. And I personally?

MODERATOR: Uh huh.

A PARTICIPANT: (Laughter) Don't like it.

MODERATOR: You don't like this?

A PARTICIPANT: Yeah.

MODERATOR: What other things? Okay. Before you explain --

A PARTICIPANT: I don't -- oh, okay.

MODERATOR: Because -- okay, we'll go to why. What other things?

A PARTICIPANT: Cold pasteurization. That's the same thing as irradiation?

MODERATOR: Yeah. We are talking --

(Simultaneous discussion)

A PARTICIPANT: This is what Michelob or one of the beers is cold pasteurized (Laughter).

MODERATOR: Uh huh. So how do you like this? Cold pasteurization?

A PARTICIPANT: Just words.

A PARTICIPANT: Sounds like beer.

A PARTICIPANT: Just like you were saying, it's just a twist of words.

A PARTICIPANT: Uh huh.

MODERATOR: Uh huh.

A PARTICIPANT: No one knows what (indiscernible) -- you know, what they're going to do with radiated food, so they're just going to go to the old pasteurization word just to twist you around.

A PARTICIPANT: Pasteurization has been around for a very, very long time. And we're very comfortable with it.

A PARTICIPANT: Right.

A PARTICIPANT: No one ever questions -- I certainly don't ever question when a product is pasteurized. I don't know when I see the words electronic and cold and ion in front of it, what the hell that means.

A PARTICIPANT: Really. You know? Because it isn't -- pasteurization is when you heat it up. Right? So isn't cold pasteurized just pasteurization that just --

A PARTICIPANT: When you freeze it?

A PARTICIPANT: Exactly.

A PARTICIPANT: A lot of people --

A PARTICIPANT: It's an oxymoron. You can't heat something up and it be cold. Unless

you're going to freeze it or do some kind of liquid nitrogen or something like that.

MODERATOR: Uh huh. Barbara?

(Simultaneous discussion)

MODERATOR: Barbara, you said something.

A PARTICIPANT: Yeah. I think it's just pulling in the old word that we're used to.

A PARTICIPANT: Well, they're throwing in some new ones. I feel like I need to be a rocket scientist to know what that means.

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A PARTICIPANT: Isn't pasteurization and irradiation separate? Aren't they separate methods? So how would pasteurized by irradiation be --

MODERATOR: Uh huh.

A PARTICIPANT: They're using both methods.

A PARTICIPANT: Yeah. They used both methods in the sentence, but I don't think they use both methods.

A PARTICIPANT: It's not an accurate reflection of what's really happening.

A PARTICIPANT: Exactly.

MODERATOR: Okay. So this makes you think -- this pasteurized by irradiation -- it makes you think that there were two methods used.

A PARTICIPANT: Yeah.

A PARTICIPANT: No. It makes me think they think I'm stupid enough to go through with and go, oh, but it's pasteurized (inaudible) --

A PARTICIPANT: Yeah, right.

A PARTICIPANT: And that's not -- I don't like it when they play mind games with me like that

MODERATOR: And it's (indiscernible) -- you wanted to say something?

A PARTICIPANT: Well, I might, because I don't completely understand irradiation yet. And I don't feel like I've been properly educated. When I look at these two, I don't know what that means.

A PARTICIPANT: Right.

MODERATOR: Uh huh.

A PARTICIPANT: That's meaningless to me. I'm pretty sure I remember what pasteurization

is. Unless you give me a definition like that and you tell me what -- MODERATOR: But wait here. We have this definition. Yes?

A PARTICIPANT: Right.

MODERATOR: So we know what --

A PARTICIPANT: It sounds like a contradiction in terms. Irradiation is a -- is something

that's like pasteurization, so how can it be pasteurized by something that it's like?

MODERATOR: Uh huh. Uh huh.

A PARTICIPANT: If you give me that definition, this still doesn't make sense to me.

MODERATOR: Okay. So you don't like pasteurized by irradiation. But what about treated by

cold pasteurization? What about that?

A PARTICIPANT: I don't like using the word "pasteurization" at all.

A PARTICIPANT: Because it sounds like some rich Viennese guy did it. Good old ion pasteurization. I'm a fan of this. No, seriously, I'm going to be honest. I don't like any of them. I have no opinion on it. I don't like any of those.

MODERATOR: Uh huh. And why is that?

A PARTICIPANT: Because they're trying to fool you (Laughter). Pasteurization has nothing to do with irradiation. A process like. Doesn't say is. I don't like that.

MODERATOR: Okay. Christy?

A PARTICIPANT: I agree with Ryan. I don't like any of them. I don't like using the word pasteurization at all.

MODERATOR: Okay. I have one last question. I have one more question. Who should decide the wording of these statements? Should it be manufacturers or it should be prescribed by a regulation?

A PARTICIPANT: How about the Surgeon General?

MODERATOR: Uh huh.

A PARTICIPANT: So it could kind of sit in the middle. Because if you let the companies do that, pasteurization will be all over it.

A PARTICIPANT: Uh huh. A PARTICIPANT: Uh huh.

California, July 9 – 8:00 p.m.

MODERATOR: Okay. In this case, I want to show you letter (inaudible). Let me put this one away, please (inaudible).

(Simultaneous discussion)

MODERATOR: And I have to mention that this local goal is the symbol (sic). Yes? So (inaudible) all go with the symbol?

A PARTICIPANT: Yeah. Just (inaudible) --

MODERATOR: Statement that would go to the symbol.

A PARTICIPANT: Pasteur did not invent this process (Laughter).

MODERATOR: Uh huh.

A PARTICIPANT: Louis Pasteur, the guy who started boiling stuff and getting them to be

pasteurized? He didn't make this up, so I don't really like it off the bat.

MODERATOR: Uh huh.

A PARTICIPANT: Because it's not him. It's not his process. That's something completely different. As to it boiling, well I'll tend to go with that. And now it's treated by electronic pasteurization (inaudible) up to it and (inaudible). (Laughter)

(Simultaneous discussion)

A PARTICIPANT: It's not being pasteurization.

A PARTICIPANT: By using a word that we already know. Pasteurization.

MODERATOR: So what are you saying?

(Simultaneous discussion)

A PARTICIPANT: It's trying to fake you out. They just add their word, pasteurized (inaudible) --

(Simultaneous discussion)

A PARTICIPANT: That's one that we're comfortable with, and --

A PARTICIPANT: Pasteurized by irradiation meaning that -

A PARTICIPANT: It's safe.

A PARTICIPANT: Because we already know it. Pasteurization.

A PARTICIPANT: I like the cold pasteurization.

MODERATOR: You do? A PARTICIPANT: Yeah.

(Simultaneous discussion)

MODERATOR: So do you think it's a good idea to use the B?

(Simultaneous discussion)

A PARTICIPANT: Yeah.

A PARTICIPANT: You slip it right by everybody.

MODERATOR: But how would you feel? If you've seen this type of writing on irradiated food? You know a little bit about it -- I (inaudible) the definition. I read you an FDA statement. A PARTICIPANT: I think the cold pasteurization is misleading. As a consumer, if I saw that, I might buy it, whereas I don't want to eat this food. So, seeing that would be like cold pasteurization, okay. It's pasteurized. The electronic pasteurization, ion pasteurization, and if it says irradiation it seems more truthful to me. And it ties in with what I've heard. Cold pasteurization is like, where did this come from? I don't --

MODERATOR: Okay, okay. So we mentioned here ion pasteurization. What do you think about this (inaudible)? Treated by ion pasteurization.

A PARTICIPANT: It's cheating.

(Simultaneous discussion)

MODERATOR: Cheating? Why is it cheating?

A PARTICIPANT: It's not irradiation anymore. It's ion pasteurization. It looks — in my mind, it looks to be two totally separate (inaudible) things. This one might be tomorrow. You know, it might not have even existed yet. I would not know the difference, because I don't know what this one is. But I knew what the one before was. This is a totally different —

MODERATOR: The one before that was B and A. Yes?

A PARTICIPANT: Cold pasteurization. That's something to do with freezing and killing bacteria. It's nothing to do with radiation. It's nothing to do with ion accelerator, gamma rays and materials that are radiation. That's very misleading.

MODERATOR: What do you think? What do other people think about ion pasteurization?

A PARTICIPANT: It seems pretty deceptive.

A PARTICIPANT: It's deceptive.

A PARTICIPANT: Uh huh.

A PARTICIPANT: It's sort of like frozen steam (Laughter). Because it's not pasteurization.

Pasteurization is really old. And Luis Pasteur would be able to spin in his grave.

A PARTICIPANT: Yeah.

A PARTICIPANT: When I see ion pasteurization, I think they're trying to make me identify with pasteurization which I know, and then deceive me with ion, because I don't know what that is. And so I feel deceived by that statement.

A PARTICIPANT: That's some psychology right there.

MODERATOR: But what about electronic pasteurization?

A PARTICIPANT: It's the same. A PARTICIPANT: The same.

A PARTICIPANT: They're all along the same lines. Pasteurization is the changing of that word. They went from radiation to irradiation to pasteurization. And they're two different processes, so they're switching around with the other, just -- They're pulling the wool over your eyes. It's not the same process. If they said that, I wouldn't think it was irradiation.

MODERATOR: And Louise, what do you think?

A PARTICIPANT: Well, I think that bottom one, they used pasteurized by irradiation because we know --

MODERATOR: Yeah, well, we would go --

(Simultaneous discussion)

A PARTICIPANT: - pasteurization.

MODERATOR: Okay. So we want to talk about this. What do you think -- pasteurized by irradiation?

A PARTICIPANT: The same. It's safe because we already know what pasteurization is. It kills germs. So if it's pasteurization, it's -- that's (inaudible) by irradiation. Oh that's new, but they killed it, so it would still be (inaudible) --

A PARTICIPANT: They still do it.

MODERATOR: So what do you think? Pasteurization irradiation?

A PARTICIPANT: I think that sounds more truthful than the B1 choices. It sounds more like what it really is.

A PARTICIPANT: Uh huh.

A PARTICIPANT: I agree. And I think they just — it sounds definitely as — out of all of them, the most like the true process. But it is another way with the pasteurized — you get that little (inaudible) in there.

MODERATOR: Uh huh. Albert, what do you think? Pasteurization by irradiation. A PARTICIPANT: I just really have a tough time with it -- with them using the word

pasteurized. It's so -- you get so used to seeing it on dairy products that anything left in that, it makes you step back and think (inaudible) -- what is -- wait a minute. How can this be?

**EXECSEC** 

## Dr. Bernard Schwetz et al.

You know? And if you have to stop and think one, two, three -- put the product back on the shelf.

A PARTICIPANT: It's easy.

A PARTICIPANT: You know. Just make it easy for me to put it in the cart. And it's - if you put it really, really small on the bottom and I don't have to see it, then I won't think about it and I'll just eat it.

MODERATOR: And Debbie, what do you think about this? Pasteurization by irradiation.

What do you think about that?

A PARTICIPANT: I'm not sure. I'm not sure about that one. I know the first -- the one in C1, those three all sound too complicated to me. If (inaudible phrase) losing (inaudible).

Pasteurized by irradiation sounds better. It sounds better to me.

MODERATOR: But in what sense? Why does it sound better?

A PARTICIPANT: The others sound so technical. Ions, electronics. You know, things like that. I guess that must be reason.

MODERATOR: Anything to add on this pasteurized by irradiation? Anyone have something to add (inaudible)?

(No response heard.)

MODERATOR: Okay. So the last one. Treated by cold pasteurization. Again (inaudible) irradiation. What if this was on the label?

A PARTICIPANT: Well, it's good that they have irradiation (inaudible).

A PARTICIPANT: I think the -- (Simultaneous discussion)

A PARTICIPANT: They take cold pasteurization and the irradiation, which basically they're trying to make it — it's the same thing. Of course that's what it means. But they're trying to make the irradiation sound just a little bit nicer by matching it to cold pasteurization. So, you're thinking well, okay, I don't really know what irradiation means, but cold pasteurization sounds like something I know, so okay, it must be okay.

MODERATOR: So would you pick this one? You like that one?

A PARTICIPANT: No, I wouldn't pick that one. I would definitely pick the very last one, just because it does sound just a little more close to what the actual process is happening -- it's pasteurized by irradiation. It's cleansed and the bacteria removed and killed and -- by this. Just because you don't know what it is doesn't mean it's going to make a difference to many people. Some people are not going to care what it is.

MODERATOR: And Amina, how about you? What do you think about this one? Pasteurized by irradiation.

A PARTICIPANT: I agree with Lois about pasteurized by irradiation because we're familiar with pasteurization.

MODERATOR: Un huh. Yeah.

A PARTICIPANT: I think that's a cleansing process, and the irradiation, as Cheryl said, doesn't sound so bad when it's connected with the pasteurization. But as I said before, I think that all of these are designed to deceive me, and I wouldn't buy it. It wouldn't cause me to buy the product.

MODERATOR: And Josh, your opinion about treated by cold pasteurization. (inaudible) irradiation.

A PARTICIPANT: It's still pasteurization.

MODERATOR: Uh huh.

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A PARTICIPANT: It's in the least mislcading, slightly. To think, I don't know, the definition should be right (inaudible phrase) that would be (inaudible). I don't know. Irradiation is still (inaudible), so it's treated by irradiation in essence. But cold pasteurization sounds so much cleaner and so much less involved. So it's so much more simple, that they can get away with putting it that way. I don't know. It's misleading. Why would they do that?

## Minnesota, July 7-6:00 p.m.

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MODERATOR: Okay. So, now, I would like to show you the third one. This is our last option. We'll have three, all together. This is Option C. Let's see what we have here. "Treated by electronic pasteurization"; "Treated by cold pasteurization"; "Treated by ion pasteurization." What do you think about that one?

PARTICIPANT: I don't know what they are.

PARTICIPANT: I don't, either.

PARTICIPANT: I don't have a clue, so it doesn't mean anything.

PARTICIPANT: We're familiar with the term "pasteurization." So, "Treated by cold pasteurization," you automatically think, "Oh, that's how milk is done. This is safe."

PARTICIPANT: But it doesn't tell you how.

PARTICIPANT: But I think, if you're in the store and you're just buying, I just think very few people really stop and think, "I wonder how this was prepared or processed?" I don't. When a new product comes out, if it looks good (indiscernible).

MODERATOR: But would this be a good idea, to put this (indiscernible)?

PARTICIPANT: I think it's almost misleading to use the term "pasteurization," if it's a different process. If it's using radiation, I think it needs to be in there that it's radiation, somehow; whether it's "irradiation" or whatever. That way, people know that it's different.

MODERATOR: But you told me, before, that people don't know what irradiation is.

PARTICIPANT: Right.

MODERATOR: Here, they would have something familiar, something they can relate to.

PARTICIPANT: To be honest, I don't think many people know what pasteurization is; we just know that they do it.

PARTICIPANTS: Yes.

PARTICIPANT: We don't know what it is but we know that they do it and we know that they do it to our milk and sometimes some other things.

MODERATOR: So, maybe, therefore, it would be better to use this terminology because people are familiar?

PARTICIPANT: If it's the same thing. I mean, I don't know. I don't know enough about pasteurization and radiation and if it's the same thing.

PARTICIPANT: As long as it's not misleading.

PARTICIPANT: If it's a completely different process, then I don't think it's okay just to add a word, like "electronic" or "ion."

PARTICIPANT: Well, "ion" kind of is another one of those things where you --

PARTICIPANT: Right -- a little disturbing.

PARTICIPANT: Yeah.

PARTICIPANT: Well, I mean, "electronic."

PARTICIPANT: Yeah, what's that?

PARTICIPANT: And, to me, when I see "Treated by cold pasteurization," I think, what's the

difference between that and what they do to my milk? I mean, my milk is cold and it's

pasteurized. Is there a difference?

PARTICIPANT: I wouldn't have even thought about it if they put it in either one of these terms because we are familiar with the word "pasteurization." So, if they put one of these words in front of it, I don't know if we still would — it still might be ignored. I don't know. We might not ignore it, though.

PARTICIPANT: I think, if I saw any of these on a package, I probably wouldn't buy it. I would

go after something that didn't have it on there because I don't know what this is.

PARTICIPANT: Yesh.

PARTICIPANT: Can I say something about C, too?

MODERATOR: Actually, we didn't talk about this one.

PARTICIPANT: C-2 bothers me, when we're looking at C-1 because, in C-1, you're saying that it's pasteurized. You're replacing the term "irradiation" with "pasteurization." In C-2, you're saying it's pasteurized by irradiation. It's like defining a word by using the word to define it. It's either irradiated or it's pasteurized. You're mixing two processes there. And people really aren't familiar with either one, as far as how it's done. And when you put them both together, "Holy mackerel, what are they doing to my food?"

MODERATOR: I would like to come back here, very quickly, because I didn't ask you about this. What did the rest of you think about "Pasteurized by irradiation"? What do you think about that one?

PARTICIPANT: It is kind of confusing because it's, like, are they two different processes? Is irradiation a type of -- I mean, I don't know what that is.

PARTICIPANT: I don't think we understand either term very well, so I think it's completely confusing.

MODERATOR: It's explaining an unknown by an unknown.

PARTICIPANT: I'm thinking of pasteurization. Didn't they used to heat it to get all the bacteria out? So that's kind of what pasteurization is. Then, irradiation would be zapping it. It's maybe doing the pasteurization quick.

PARTICIPANT: But if pasteurization is heating it, how can they say they're treating --

PARTICIPANT: They're treating it with radiation

PARTICIPANT: Then how can they say, "Treated by cold pasteurization"? If pasteurization is heating, how can you do that with cold?

PARTICIPANT: See, we don't know if it's two different processes, though? One possibly could be a cold process and one could be another type of process.

MODERATOR: So, which one would be cold and which one would be another?

PARTICIPANT: That's what I'm saying.

PARTICIPANT: I don't know.

(Indiscernible simultaneous discussion.)

PARTICIPANT: If one is cold and one is hot, you can't do them at the same time.

PARTICIPANT: Right.

PARTICIPANT: Because then you'd just have lukewarm.

MODERATOR: I guess you are talking about this one: "Treated by cold pasteurization," in parenthesis, "irradiation." Isn't it the best explaining to you? What do you think about that?

PARTICIPANT: No. PARTICIPANT: Huh-uh.

PARTICIPANT: So, now, you've put two terms in there that people don't really know what they

mean

PARTICIPANT: Yeah. Because those two words, we don't know if they mean the same thing — well, it couldn't mean the same thing.

MODERATOR: Do you mean pasteurization and irradiation?

PARTICIPANT: Uh-huh.

MODERATOR: But how does that make you feel? -- "Treated by cold pasteurization," and,

then, in parenthesis, "irradiation."

PARTICIPANT: It doesn't help.

PARTICIPANT: It makes me feel like we should be seeing the symbol for the fallout shelter.

PARTICIPANT: That's what I thought of.

MODERATOR: And when you look at all those three pages, are any of those statements a no-no, and should not be on the label?

PARTICIPANT: All of C.

PARTICIPANTS: C.

PARTICIPANT: Well, all of A, for me. If you could replace A with B-1, either the first one or the third one, I think you'd get rid of all of A. Because B-1, the first one and the last one, are much less—I don't know. "Treated by radiation" gives you a cold feeling. It's not a really happy thought. When you're "destroying harmful bacteria" and you're "improving food safety," people feel much nicer about their food, if they read that, than just "treated by irradiation."

MODERATOR: But I understand that you said a definite no-no to C; is that right?

PARTICIPANTS: Yes.

MODERATOR: Why is that?

PARTICIPANT: I don't think it sounds very pleasant. When you're buying food, you think of happy things. Most of us, when we eat, think, "Wonderful."

PARTICIPANT: Go shopping for a party: "Oh, 'ion pasteurized.' Well, eat up, everybody. It's been treated with ion pasteurization."

MODERATOR: Okay. So you were pretty consistent on what statement to choose for the label. Should the wording on the statement be regulated? Should it be proscribed by regulation? Or should it be up to the manufacturers to choose different wording?

PARTICIPANTS: Regulated.

MODERATOR: Why do you say that? Why do you think that?

PARTICIPANT: Well, because this is a perfect example of how you can play with words to make different things — you know. Like we said, we picked this one because it sounded more positive.

PARTICIPANT: A good feeling about it.

PARTICIPANT: Yeah. And if there is a chance, you know, especially when you talk about radiation. I think you need to know -- you need to inform people.

MODERATOR: So the regulations should require the ones that you picked; is that right?

PARTICIPANT: Uh-huh.

In sum, the comments on the topic decisively reject the proposed substitution of "pasteurized" for "irradiated" as misleading. The phrases in bold, above, show the focus group members were separately, promptly, and spontaneously motivated to unleash a creative variety of harsh condemnations for this deception. Further, the groups were notably fearful about the potential for the FDA's suggestions as far commingling the two terms to reduce the public's future trust in the term "pasteurized," a traditional food process that consumers understand. (As one individual in the 8:00 p.m. California session vividly put it: "Luis Pasteur would be able to spin in his grave.") The degree of consensus against the proposed changes across the country was remarkable.

As we additionally documented for you in our letter of June 1, a decision by you contrary to the clear consensus of the focus groups would be breathtakingly arbitrary and capricious. Please contact Peter Jenkins, Attorney/Policy Analyst of CFS (tel: 202.547.9359 x13; email: peterjenkins@icta.org) if you would like to discuss this further.

Sincerely,

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